APPROPRIATE PRESCRIBING OF SPECIALIST INFANT FORMULAE

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Colour key used on the following pages:

- **Prescribe as first line**
- **Prescribe as second line**
- **Should not routinely be commenced in primary care**
- **Should not routinely be prescribed**
- **Grey list formulae – to be purchased over the counter from supermarket or pharmacy**

Ratified by: BBCCG Prescribing Group 18.9.18
TCCG Medicines Management and Safety Group 5.10.18
Medicines Management Committee 30.11.18 and amended 25.01.19

Review date: October 2019
Author: Medicines Optimisation Team, Thurrock CCG, Tel: 01375 365811

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INTRODUCTION

Whilst these guidelines advise on appropriate prescribing of specialist infant formulae, breast milk remains the optimal milk for infants. This should be promoted and encouraged where it is clinically safe to do so and the mother is in agreement.

PURPOSE OF THE GUIDELINES

These guidelines aim to assist GPs and other practice staff, Health Visitors, Dietitians and hospital medical staff with information on the use of prescribable infant formula. The guidelines are targeted at infants 0-12 months. However, some of the prescribable items mentioned here can be used past this age and advice on this is included in the guidelines. The guidelines advise on:

- over the counter products available where appropriate
- initiating prescribing
- quantities to prescribe
- which products to prescribe for different clinical conditions
- triggers for reviewing and discontinuing prescriptions
- when onward referral for dietetic advice and/or secondary/specialist care should be considered

QUANTITIES OF FORMULAE TO PRESCRIBE

When any infant formula is prescribed the guide below should be used:

For powdered formula:

<table>
<thead>
<tr>
<th>Age of child</th>
<th>Number of tins for 28 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 6 months</td>
<td>13 x 400g tins or 6 x 900g tins</td>
</tr>
<tr>
<td>6-12 months</td>
<td>7-13 x 400g tins or 3-6 x 900g tins</td>
</tr>
<tr>
<td>Over 12 months</td>
<td>7 x 400g tins or 3 x 900g tins</td>
</tr>
</tbody>
</table>

These amounts are based on:

- Infants under 6 months being exclusively formula fed and drinking 150ml/kg/day of a normal concentration formula.
- Infants 6-12 months requiring less formula as solid food intake increases.
- Children over 12 months drinking the 600mls of milk or milk substitute per day recommended by the Department of Health.

For liquid high energy formula:
Prescribe an equivalent volume of formula to the child’s usual intake until an assessment has been performed and recommendations made by a paediatrician or paediatric dietitian.

N.B. Some children may require more eg. those with faltering growth.
N.B. Review recent correspondence from the paediatrician or paediatric dietitian.

The dietitian may suggest formula which are not first line if these are felt to be more clinically appropriate for the infant. When requesting a prescription which is not for a first line product, the clinical justification should be included with the prescription request.
The CMA template on SystmOne guides users on the symptoms, diagnosis and locally agreed management pathway for CMA. The template includes a symptom score (CoMiSS) to aid diagnosis (shown below) and a locally agreed milk allergy pathway and management strategy (pages 4 and 5).

CoMiSS: Cow’s Milk-related Symptom Score

<table>
<thead>
<tr>
<th>SYMPTOM</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Crying</strong></td>
<td></td>
</tr>
<tr>
<td>0 ≤ 1 hour/day</td>
<td></td>
</tr>
<tr>
<td>1 1 to 1.5 hours/day</td>
<td></td>
</tr>
<tr>
<td>2 1.5 to 2 hours/day</td>
<td></td>
</tr>
<tr>
<td>3 2 to 3 hours/day</td>
<td></td>
</tr>
<tr>
<td>4 3 to 4 hours/day</td>
<td></td>
</tr>
<tr>
<td>5 4 to 5 hours/day</td>
<td></td>
</tr>
<tr>
<td>6 ≥ 5 hours/day</td>
<td></td>
</tr>
<tr>
<td><strong>Regurgitation</strong></td>
<td></td>
</tr>
<tr>
<td>0 0 to 2 episodes/day</td>
<td></td>
</tr>
<tr>
<td>1 ≥ 3 to ≤ 5 of small volume</td>
<td></td>
</tr>
<tr>
<td>2 &gt; 5 episodes of &gt; 1 coffee spoon</td>
<td></td>
</tr>
<tr>
<td>3 &gt; 5 episodes of half of the feeds in &lt; half of the feeds</td>
<td></td>
</tr>
<tr>
<td>4 Continuous regurgitations of small volumes &gt; 30 min after each feed</td>
<td></td>
</tr>
<tr>
<td>5 Regurgitation of half to complete volume of a feed in at least half of the feeds</td>
<td></td>
</tr>
<tr>
<td>6 Regurgitation of the complete feed after each feeding</td>
<td></td>
</tr>
<tr>
<td><strong>Stools</strong> (Bristol scale)</td>
<td></td>
</tr>
<tr>
<td>4 Type 1 and 2 (hard stools)</td>
<td></td>
</tr>
<tr>
<td>0 Type 3 and 4 (normal stools)</td>
<td></td>
</tr>
<tr>
<td>2 Type 5 (soft stool)</td>
<td></td>
</tr>
<tr>
<td>4 Type 6 (liquid stool, if unrelated to infection)</td>
<td></td>
</tr>
<tr>
<td>6 Type 7 (watery stools)</td>
<td></td>
</tr>
<tr>
<td><strong>Skin symptoms</strong></td>
<td></td>
</tr>
<tr>
<td>0 to 6</td>
<td></td>
</tr>
<tr>
<td>Atopic eczema</td>
<td></td>
</tr>
<tr>
<td>Head-neck/trunk</td>
<td></td>
</tr>
<tr>
<td>Arms-hands-feet</td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory symptoms</strong></td>
<td></td>
</tr>
<tr>
<td>0 No respiratory symptoms</td>
<td></td>
</tr>
<tr>
<td>1 Slight symptoms</td>
<td></td>
</tr>
<tr>
<td>2 Mild symptoms</td>
<td></td>
</tr>
<tr>
<td>3 Severe symptoms</td>
<td></td>
</tr>
</tbody>
</table>

* Crying only considered if the child has been crying for 1 week or more, assessed by the parents, without any other obvious cause.

**Reading the Result**

The scoring ranges from 0 to 33. Each symptom has a maximal score of 6, except respiratory symptoms where the maximal score is 3.

- If final score ≥ 12, the symptoms are likely cow’s milk-related. This could potentially be CMPA.
- If final score < 12, the symptoms are less likely related to cow’s milk. Look for other causes.

CMPA diagnosis can only be confirmed by an elimination diet followed by an oral food challenge.

Primary Care Milk Allergy Pathway in South West Essex

Daily Crying ≥ 2hrs +/- Vomiting >5 episodes
Vomiting > half of volume or continuous regurgitation > 30 minutes after feed
 +/- Eczema +/- type 1 or 2 or 6 or 7 in Bristol stool chart

- GP Review
- Out of Hours Service
- Health Visitor Review

Red Flags identified
- Hives, lip/tongue swelling within 2 hours
- Above symptoms +/- wheeze, cough, voice change
- Increased heart rate, colour change within 2 hours
- Blood in stool
- Fattening growth in spite of adequate feeding
- Persistent diarrhoea/vomiting

PAU/Hospital Referral
(See secondary care milk allergy pathway)

CoMMIS Score

≥12
- CMPA likely

Exclusively breast fed
- Trial maternal dairy free diet with calcium and vitamin D supplement for 2-4 weeks

Formula feeding
- Trial extensively hydrolysed formula for 2-4 weeks

Mixed Feeding
- Formula + breast
- Trial extensively hydrolysed formula for 4-7 weeks

Community Dietitian referral

If symptoms persist
- Trial extensively hydrolysed formula + maternal dairy free diet for 2-4 weeks

If CoMMIS score ≥12

Unresponsive to EFA

Symptoms resolved no red flags
- Trial Amino Acid Formula for 4 weeks

Urgent referral to local multi-disciplinary Paediatric Allergy Service

Symptoms improved but red flags identified

Milk ladder at 9-12 months
- Local management within community dietetics

Any other red flags or acute onset symptoms identified at any appointment, then refer to multi-disciplinary paediatric allergy clinic

*CMPA diagnosis can only be confirmed by an elimination diet followed by an oral food challenge
Secondary Care Milk Allergy Pathway

Referral criteria for Multi-disciplinary paediatric allergy service

- History of anaphylaxis/severe allergic reaction with one or more severe acute systemic reactions or severe delayed reactions
- Multiple food allergies
- Single/multiple food allergies with any of the following: Poorly controlled asthma
  - Severe eczema
  - Faltering Growth
  - GI symptoms
- Not responded to a single allergen elimination diet
- Clinical suspicion of multiple food allergies, including persisting parental suspicion of food allergy despite a lack of supporting history
- Strong clinical suspicion of IgE mediated food allergy but allergy test results are negative
- Chronic urticaria
- Frequent ED attendance/admission for confirmation of food allergies
- Reintroduction of known food allergens

Red Flag Symptoms

- Hives, lip/tongue swelling within 2 hours
- Above symptoms +/- wheeze, cough, voice change increased heart rate, colour change within 2 hours
- Blood in stool
- Faltering growth in-spit of adequate feeding
- Persistent diarrhoea/vomiting

Manifestation of intractable multi-organ symptoms despite optimum management, including multiple exclusion diet

Referral to tertiary centre
**COW’S MILK ALLERGY (CMA) continued**

### SYMPTOMS, DIAGNOSIS AND INITIAL INFORMATION FOR FAMILIES

- **Infants with red flag symptoms** should be referred immediately to the paediatric assessment unit in secondary care.

  **RED FLAG** symptoms include:
  1. Hives or lip/tongue/eye or facial swelling within 2 hours of consumption
  2. Above symptoms +/- wheeze, cough, voice-change, increased heart rate, colour change within 2 hours
  3. Blood in stool
  4. Faltering growth with adequate feeding
  5. Persistent diarrhoea/vomiting

- **If there are no red flag symptoms**, complete the CoMiSS questionnaire (page 3 or via the SystmOne template) and generate a score. If the score is < 12 CMA is unlikely and an alternative diagnosis should be considered.

- Often several symptoms may be present and can include:
  - Skin symptoms (pruritis, erythema, urticaria, atopic dermatitis or eczema, non-specific rashes)
  - Gastrointestinal (GI) symptoms (loose, frequent or mucus containing stools, nausea and vomiting, abdominal distension and/or colicky pain, constipation sometimes soft stools with excessive straining, GORD)
  - Recurrent wheeze or cough (but see red flag symptoms above), nasal itching, sneezing, rhinorrhea or congestion
  - Food refusal or aversion

- **If the CoMiSS score is \( \geq 12 \), follow the management algorithm on the Primary Care Milk Allergy Pathway** on page 4.


  It is important that families are made aware that cow’s milk allergy can only be confirmed by an elimination diet followed by an oral milk challenge.

### ONWARD REFERRALS

- **Most infants with CMA can be managed in primary care.**
- **Referral to a paediatric dietitian is ESSENTIAL** and should be made as soon as possible for all infants who will require a cow's milk free diet. Breastfeeding mothers following a milk free diet should also be referred to the paediatric dietitian who will advise them regarding their diet and that of their child.
- **Refer infant to secondary or specialist care** if any of the following apply:
  - Red flag symptoms
  - Severe delayed reactions
  - Possible multiple food allergies identified
  - Persisting parental suspicion of food allergy despite a lack of supporting history (especially where symptoms are difficult or perplexing)
COW'S MILK ALLERGY (CMA) continued

INITIAL MANAGEMENT FOR THE FIRST 4 WEEKS

- Refer to the locally agreed pathway on page 4

MANAGEMENT - breast fed infants

  
  It is recommended that breastfeeding mothers on a milk free diet should purchase supplementation with 1000mg calcium per day as well as the recommended 10mcg (400 units) Vitamin D.

  If breastfeeding mothers do not wish to or are unable to follow a milk free diet, or are following a milk free diet and top-ups are required, an extensively hydrolysed (EHF) formula may well be tolerated and should be prescribed. Only if EHF is not tolerated after a trial period of 4 weeks (minimum 2 weeks) should amino acid formula (AAF) be prescribed. Refer to the locally agreed formulary on page 9.

MANAGEMENT - formula fed infants

- If breastfeeding is not occurring, **EHF are the first choice**, unless the infant has a history of anaphylactic symptoms. EHF should be prescribed for a trial period of 4 weeks (minimum 2 weeks).

  AAF should not routinely be started in primary care as the first formula prescribed. They are suitable only when EHF do not resolve symptoms and/or there is evidence of severe or anaphylactic allergy. Refer to the primary care pathway on page 4.

  - If a patient has a history of anaphylactic reaction to cow's milk, AAF may be started in primary care as the first formula prescribed, with immediate onward referral to secondary or specialist care.
  - Only 10% of infants with CMA should require management with AAF.

MANAGEMENT AFTER INITIAL 4 WEEKS

If symptoms resolve during the initial 4 weeks

- For the diagnosis to be confirmed it is important to know whether this has been due to exclusion of cow's milk or is coincidental. Therefore a milk challenge is required unless red flag symptoms were present.


  If CMA is the cause of the symptoms they will reappear within a few days and cow's milk should be withdrawn again with EHF re-established or a milk free diet for breastfeeding mothers continuing until the infant is 9-12 months old.

  If the infant remains well there is no need to continue with cow's milk exclusion for breastfeeding mothers or with EHF for formula fed babies.

If symptoms do not resolve during the initial 4 weeks

- The dietitian will advise on next steps which will vary according to the clinical picture but may include exclusion of other foods such as eggs in breastfeeding mothers’ diets, or a switch to an AAF for formula fed infants.

- If multiple food allergy is suspected or if there is faltering growth a referral to secondary care is recommended.
COW’S MILK ALLERGY (CMA) continued

SUBSEQUENT MANAGEMENT OF CMA

The dietitian will advise on reintroduction of cow’s milk to the infant’s diet stepwise using a ‘milk ladder’ from the age of 9 months to 1 year. The milk ladder is available here:


Review the need for the prescription if you can answer ‘yes’ to any of the following questions:

- Is the patient over 1 year of age? Or has the formula been prescribed for more than 1 year?
- Is the patient prescribed more than the suggested quantities of formula for their age?
- Is the patient prescribed a formula for CMA but able to eat any of the following foods – cow’s milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee?

Children with multiple or severe allergies may require prescriptions beyond 1 year. This should always be at the suggestion of the paediatric dietitian.

NOTES

1. **Soya formula (SMA Wysoy®)** should not be used at all for those under 6 months due to the risk that infants with CMA may also develop allergy to soya. It is more likely that children will tolerate soya formula from 1 year. If soya formula is used, parents should be advised to purchase this over the counter as it is a similar cost to cow’s milk formula and readily available. Alpro® Soya Growing Up Drink may be suitable from 1 year. The paediatric dietitian will advise on this and on other alternative milks which may be suitable.

2. **EHF and AAF have an unpleasant taste and smell**, which is better tolerated by younger patients. Unless there is anaphylaxis, advise parents to introduce the new formula gradually by mixing with the usual formula in increasing quantities until the transition is complete. Serving in a closed cup or bottle or with a straw (depending on age) may improve tolerance.

3. **Prescribe a one week supply initially** until compliance/tolerance is established to avoid waste.

4. **If AAF are not clinically indicated they should not be prescribed.** Although EHF are not halal or kosher, if they are medically indicated a medical exemption should be sought from the local faith leader.

5. **Rice milk** is not suitable for children under 5 years due to its arsenic content.

6. **Outgrowing CMA** – 60-75% of children outgrow CMPA by 2 years of age, rising to 85-90% of children at 3 years of age.

7. **Calcium and occasionally vitamin D supplementation** may be needed for infants depending on volume and type of formula taken and the dietitian will advise on this – over the counter products are available e.g.

   - Vitabiotics Ultra Calcium which can be crushed and added to food (1 tablet gives 500mg calcium and 10mcg vitamin D)
   - Holland & Barrett chewable calcium (1 tablet gives 500mg)

8. **Lactose free formulae, goat’s, sheep’s, and other mammalian** milks are not suitable for those with CMA.
COW’S MILK ALLERGY (CMA) continued

THE MOST COST EFFECTIVE EXTENSIVELY HYDROLYSED FORMULA IS

- **Similac Alimentum®** (Abbott Nutrition)  
  Birth to 1 year or able to tolerate over the counter products. Lactose free. Casein based.

*Prescribing this EHF will give a cost saving of up to £250 in the first year of a child’s life compared with other EHF listed below*

OTHER EXTENSIVELY HYDROLYSED FORMULAE

- **Aptamil Pepti® 1** (Nutricia)  
  Birth to 6 months. Whey based.

- **Aptamil Pepti® 2** (Nutricia)  
  6 months to 1 year or able to tolerate over the counter products. Whey based.

- **SMA Althera®** (Nestle)  
  Birth to 1 year or until able to tolerate over the counter products. Whey based.

- **Nutramigen® 1 with LGG®** (Mead Johnson)  

- **Nutramigen® 2 with LGG®** (Mead Johnson)  
  6 months to 1 year or until able to tolerate over the counter products. Lactose free. Casein based. Contains probiotics.

- **Nutramigen 3 with LGG®** (Mead Johnson)  
  From 1 year. Lactose free. Casein based. Contains probiotics.

EXTENSIVELY HYDROLYSED FORMULAE WITH MEDIUM CHAIN TRIGLYCERIDES TO BE STARTED IN SECONDARY CARE

- **Pepti – Junior®** (Nutricia)  
  Birth to 1 year or until able to tolerate over the counter products

- **Pregestimil Lipil®** (Mead Johnson)  
  Birth to 1 year or until able to tolerate over the counter products

*These formulae are used where CMA is accompanied by malabsorption*

AMINO ACID FORMULAE - NOT TO BE ROUTINELY STARTED IN PRIMARY CARE

PREFERRED AMINO ACID FORMULA IS

- **Nutramigen® Puramino®** (Mead Johnson)  
  Birth until 1 year or able to tolerate over the counter products

*Prescribing this AAF will give a cost saving of up to £780 in the first year of a child’s life compared with other AAF listed below*

OTHER AMINO ACID FORMULAE

- **Neocate® LCP®** (Nutricia)  
  Birth until 1 year or when able to tolerate over the counter products

- **Neocate® Syneo®** (Nutricia)  
  Birth until 1 year or when able to tolerate over the counter products. Contains probiotics.

- **Neocate® Junior unflavoured, vanilla and strawberry flavours** (Nutricia)  
  Over 1 year

*If a patient presents with clear anaphylactic reaction to cow’s milk these AAF should be commenced in primary care, with immediate onward referral to secondary or specialist care.*

*If after 4 weeks on EHF there is no improvement in symptoms the dietitian may request a prescription for AAF as a trial.*
**PRE-TERM INFANTS**

**INDICATIONS**
- These infants will have had their pre-term nutrient enriched post discharge formula (NEPDF) commenced on discharge from the neonatal unit (NICU). It is not needed for all pre-term babies and those who do require it will be identified by NICU.
- **Pre-term infants, who are formula fed, have shown adequate growth during their NICU stay and do not have increased energy requirements should be discharged home on standard term formula.**
- NEPDF is used for some babies born < 34 weeks gestation, weighing < 2kg at birth who are not breast fed and who have higher energy requirements (e.g. on home oxygen).
- It is also used for infants who have had poor growth e.g. have crossed down >2 centiles on growth charts during their neonatal stay.
- If, following discharge, breast feeding reduces or stops and a formula is required the NICU or dietitian should advise whether a NEPDF is required or standard formula can be used.
- NEPDF should not be used in primary care to promote weight gain in patients other than babies born prematurely.
- If SMA® Gold Prem 2 is prescribed iron supplementation is recommended as 1ml Sytron® daily (5.5mg elemental iron).
- If Nutriprem® 2 is prescribed iron supplementation is not needed.

**ONWARD REFERRAL**
- These infants should already be under regular review by the paediatricians and health visitors.
- If there are concerns regarding poor growth whilst the infant is on these formulae, or there are concerns regarding growth at review one month after these formulae are stopped, a referral to the paediatric dietitian is appropriate.

**REVIEW AND DISCONTINUATION OF FORMULA**
- Monitoring of growth (weight, length and head circumference) should be carried out by the health visitor or paediatric team while the baby is on these formulae.
- **NEPDF is rarely needed beyond 3 months corrected age** and should be stopped as soon as the baby is demonstrating good catch up growth. **It is very important that these products should be discontinued at an appropriate age.**

**PRE-TERM INFANT FORMULAE USUALLY STARTED IN SECONDARY CARE**

<table>
<thead>
<tr>
<th>Formula</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMA® Gold Prem 2 powder (SMA)</td>
<td>Up to 3 months corrected age or catch up growth achieved</td>
</tr>
<tr>
<td>Nutriprem® 2 powder (Cow and Gate)</td>
<td>Up 3 months corrected age or catch up growth achieved</td>
</tr>
</tbody>
</table>

3 months corrected age = EDD + 13 weeks

**PRE-TERM INFANT FORMULAE WHICH SHOULD NOT ROUTINELY BE PRESCRIBED unless there is a clinical need e.g. immunocompromised infant**

<table>
<thead>
<tr>
<th>Formula</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMA® Gold Prem 2 liquid (SMA)</td>
<td>Up to 3 months corrected age or catch up growth achieved</td>
</tr>
<tr>
<td>Nutriprem® 2 liquid (Cow and Gate)</td>
<td>Up to 3 months corrected age or catch up growth achieved</td>
</tr>
</tbody>
</table>

Cost per 100kcal of liquids is 4-5 times cost of powders.
SYMPTOMS AND DIAGNOSIS

- UK WHO growth charts should be used to measure growth. It is not possible to detect faltering growth without using appropriate growth charts.

Early days of life
- Some weight loss in the first days after birth is normal with most infants returning to birth weight by 3 weeks of age.
- If infants in the early days of life lose more than 10% of their birth weight a clinical assessment is needed checking for signs of dehydration, illness or disorder that may account for this. Feeding history should be taken and direct observation of feeding may be required.

After the early days of life, diagnosis is made when:
- There is a fall of 1 or more weight centile spaces if birthweight was below the 9th centile.
- There is a fall of 2 or more weight centile spaces if birth weight was between the 9th and 91st centiles.
- There is a fall of 3 or more weight centile spaces if birthweight was above the 91st centile.
- Length/height as well as weight should be measured. If possible the biological parents’ heights should be obtained and if the infant’s length/height is below the range predicted from parental heights (more than 2 spaces below the mid-parental centile) this could suggest undernutrition or a primary growth disorder.
- Feeding behaviours, presence of pre-term birth, neurodevelopmental concerns, parental factors (e.g. maternal postnatal depression or anxiety) and any indicators of underlying illness (e.g.urinary tract infection, coeliac disease if taking solid foods) should be taken into account.
- It is essential to rule out possible causes for the faltering growth including safe guarding concerns and disease related/medical causes e.g. iron deficiency anaemia, constipation, GORD. If identified appropriate action should be taken.

ONWARD REFERRAL

Early days of life
- Refer to paediatric services if there is marked weight loss of more than 10% of birth weight, illness or failure to respond to feeding support.

After the early days of life
- Additional support should be offered by the health visitor and a referral to the paediatric community dietitian made. Advice on a short-term high calorie/protein diet together with advice on encouraging a good meal time pattern and behaviours will be offered.

Refer to secondary care paediatric services if there are
- Signs or symptoms that may indicate an underlying disorder
- A failure to respond to interventions delivered in primary care by the health visitor and paediatric dietitian (see ‘Treatment’ below)
- Slow linear growth or unexplained short stature
- Rapid weight loss or severe undernutrition
- Features that cause safe guarding concerns
TREATMENT

- Feeding support will be offered by the health visitor and paediatric dietitian.
- Breast feeding mothers should be encouraged to continue. Be aware that supplementary feeding with infant formula in a breastfed infant may help with weight gain, but often results in cessation of breastfeeding. Advise expressing breast milk to promote supply and feed the infant any available breast milk before giving any infant formula.
- If the infant is weaned, a short-term nutrient dense diet will be advised together with advice on encouraging a good meal time pattern and behaviours.
- If suggested by the paediatric dietitian consider a trial of a high energy formula.
- Enteral tube feeding should only be considered after assessment by a multidisciplinary team and after all other interventions have been tried with no improvement.

REVIEW AND DISCONTINUATION OF TREATMENT

- All infants on high energy formula will need growth (weight and height/length) monitored to ensure catch up growth occurs.
- Once this is achieved the high energy formula should be discontinued to minimise excessive weight gain and to avoid reducing an infant’s appetite for other foods.
- Withdrawal may need to be phased and the dietitian will advise.

HIGH ENERGY FORMULA FIRST LINE

<table>
<thead>
<tr>
<th>Formula</th>
<th>Suitable for</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMA® High Energy 200ml bottle</td>
<td>Birth up to 18 months</td>
</tr>
<tr>
<td>(SMA Nutrition)</td>
<td></td>
</tr>
</tbody>
</table>

HIGH ENERGY FORMULAE SECOND LINE

<table>
<thead>
<tr>
<th>Formula</th>
<th>Suitable for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similac® High Energy 200ml bottle</td>
<td>Birth up to 18 months or 8kg</td>
</tr>
<tr>
<td>(Abbott Nutrition)</td>
<td></td>
</tr>
<tr>
<td>Similac® High Energy 48 x 60ml bottle</td>
<td>Birth up to 18 months or 8kg</td>
</tr>
<tr>
<td>Infatrini® 100/200ml bottle (Nutricia)</td>
<td>Birth up to 18 months or 8kg</td>
</tr>
</tbody>
</table>

HIGH ENERGY FORMULA TO BE STARTED IN SECONDARY CARE

<table>
<thead>
<tr>
<th>Formula</th>
<th>Suitable for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infatrini Peptisorb® 200ml bottle</td>
<td>Birth up to 18 months or 8kg</td>
</tr>
</tbody>
</table>

NOTES

1. For otherwise healthy term infants who are born with birthweight <10th centile (small for gestational age), current evidence suggests that it is not beneficial to promote catch up growth in these infants, as it may increase later risk of obesity and metabolic disease. If they are otherwise healthy, they should be breast fed or fed with a standard term formula.
2. Where all nutrition is provided via NG/NJ/PEG tubes, there should be no need for prescriptions to be written as tube feeds are supplied on contract and ordered (off FP10) by the dietitians.
3. The paediatric dietitian will advise on appropriate monthly amounts of formula required which may exceed the guideline amounts for other infants. These formulae are not suitable as a sole source of nutrition for infants over 8kg or 18 months of age.
4. Do not add formula to repeat templates as ongoing need for formula and amount needed will need to be checked with each prescription request.
5. Manufacturers instructions regarding safe storage once opened and expiry of ready to drink formulae should be adhered to – this may differ from manufacturer to manufacturer.
GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

SYMPTOMS AND DIAGNOSIS

- Please refer to NICE Guideline NG1 Jan 2015 Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people [https://www.nice.org.uk/guidance/ng1](https://www.nice.org.uk/guidance/ng1)
- GORD is the presence of troublesome symptoms (e.g. discomfort or pain) or complications (e.g. oesophagitis or aspiration) arising from gastro-oesophageal reflux.
- Over 50% of babies experience non-distressing regurgitation, and reassurance should be given that this will improve over time.
- Symptoms of GORD may include distressed behaviour (e.g. excessive crying, crying while feeding, adopting unusual neck postures), hoarseness and/or chronic cough, a single episode of pneumonia, unexplained feeding difficulties, faltering growth.
- Regurgitation and GORD usually begin before the age of 8 weeks and resolve in 90% of infants before they are 1 year old.
- **Overfeeding needs to be ruled out** by establishing the volume and frequency of feeds. Average requirements of formula are 150mls/kg/day for babies up to 6 months, and should be offered spread over 6-7 feeds.

ONWARD REFERRAL

- Same-day admission should be arranged if the child has haematemesis (not caused by swallowed blood from a nosebleed or cracked nipple), melaena or dysphagia.
- Infants with faltering growth as a result of GORD should be referred to paediatric services without delay.
- Uncertain diagnosis or red flag symptoms suggesting a more serious condition, recurrent aspiration pneumonia or unexplained apnoeas should also prompt urgent referral for specialist assessment.
- If symptoms do not improve 4 weeks after commencing treatment as below, refer to a paediatrician for further investigations. CMA can co-exist with GORD and treatment as for CMA may be required with a trial of EHF initiated.

TREATMENT, REVIEW AND DISCONTINUATION OF TREATMENT

- **If infant is thriving and not distressed by regurgitation** reassure parents and monitor.
- Provide advice on avoidance of overfeeding, positioning during and after feeding, and activity after feeding.
- Where there is evidence of GORD, provide advice as above and if not helpful after 1-2 weeks treat as below (see overleaf for medication advice).

<table>
<thead>
<tr>
<th>STEP 1 breast fed infants</th>
<th>STEP 1 formula fed infants</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 week trial of Gaviscon Infant® may be considered. Mix each dose with 5ml (1 teaspoon) of boiled cooled water to make a smooth paste. Add another 10ml (2 teaspoons) of boiled cooled water and mix. Part way through the feed use a spoon or feeding bottle to give the dose of Gaviscon® Infant.</td>
<td>Sequential 1-2 week trial of each of the following options: 1. <strong>Thickened formula to purchase</strong> - SMA® Anti-Reflux, Aptamil® Anti-Reflux or Cow &amp; Gate® Anti-Reflux formula or Instant Carobel® added to regular formula. <strong>Or thickening formula to purchase</strong> - Enfamil AR® (see notes page 10) If these are ineffective trial Gaviscon Infant®. This should not be used with other preparations containing thickening agents. 2. <strong>Gaviscon Infant®</strong>. Mix the dose into 115ml of regular formula feed in the bottle, shake well and feed as normal.</td>
</tr>
</tbody>
</table>

Gaviscon Infant® can also be given (after mixing with boiled cooled water) at the end of each meal using a spoon or feeding bottle.

**If STEP 1 treatment is successful** continue, but stop every 2 weeks to see if symptoms improve and treatment can be stopped.

<table>
<thead>
<tr>
<th>STEP 2 for breast and formula fed infants</th>
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</thead>
<tbody>
<tr>
<td><strong>If STEP 1 treatment is not successful</strong> a 4 week trial of omeprazole or ranitidine may be considered. <strong>If symptoms persist despite medication, the child should be referred for specialist assessment.</strong> Infants with GORD will need regular review to check symptoms and growth</td>
</tr>
</tbody>
</table>
GASTRO-oesophageal reflux disease (GORD) cont’d

THICKENED FORMULAE TO PURCHASE FROM SUPERMARKETS

- SMA® Anti-Reflux from birth
- Aptamil® Anti-Reflux from birth
- Cow & Gate® Anti-Reflux from birth
- HiPP® Anti-Reflux from birth

OR THICKENING FORMULA TO PURCHASE FROM PHARMACIES

- Enfamil® AR® from birth

OR THICKENER TO PURCHASE FROM PHARMACIES FOR ADDITION TO REGULAR FORMULA

- Instant Carobel® (Cow and Gate) from birth

NOTES ON THICKENED AND THICKENING FORMULAE AND THICKENER

1. SMA® Anti-Reflux formula is thickened with potato starch. Aptamil® Anti-Reflux, Cow & Gate® Anti-Reflux and HiPP Anti-Reflux formulae are pre-thickened with carob gum. A large hole (fast flow) teat will be needed. They are available over the counter in supermarkets at a similar cost to regular formulae and are not for prescription.

2. Thickening formula (Enfamil AR®) is no longer recommended for prescription because of the ready availability of thickened formulae from supermarkets. If parents choose to purchase thickening formula, this would need to be ordered from a pharmacy and they should be advised not to use in conjunction with separate thickeners or with medication such as Gaviscon Infant®, ranitidine, or omeprazole. This formula needs to be mixed with fridge cooled pre-boiled water (see tin for full instructions).

3. Instant Carobel® feed thickener contains carob gum, is mixed with regular formula to produce a thickened formula and will require the use of a large hole (fast-flow) teat. It may be suggested for addition to EHF or AAF where CMA co-exists with GORD. Parents should purchase the thickener at a pharmacy.

4. Do not use Gaviscon Infant® with feed thickener, thickened feeds or thickening formulae, as this could lead to over thickening of the stomach contents.

NOTES ON MEDICATION (BNF for children 2017-2018, SPC for products)

1. Gaviscon Infant® contains sodium, and should not be given more than 6 times in 24 hours or where the infant has diarrhoea, vomiting, renal impairment or a fever. It should not be given if intestinal obstruction is suspected or in pre-term neonates. Each half of the dual sachet of Gaviscon Infant® is identified as ‘one dose’. To avoid errors, prescribe with directions in terms of ‘dose’. Dispensing pharmacists should advise about appropriate doses of over the counter products.

   - Weight less than 4.5kg: prescribe 1 dose, mixed with feeds when required, up to 6 times in 24 hours (maximum 6 doses in 24 hours).
   - Weight 4.5kg and above: prescribe 2 doses, mixed with feeds when required, up to a maximum of 6 times in 24 hours (maximum 12 doses in 24 hours).

2. Ranitidine – the recommended dose of ranitidine is:
   - Aged 1-5 months: 1mg/kg 3 times daily (maximum 3mg/kg 3 times daily)
   - Aged 6 months to 2 years: 2 - 4mg/kg twice daily
   - Ranitidine is available as 5mg/5ml oral suspension (unlicensed liquid special)

3. Omeprazole – the recommended dose of omeprazole is:
   - Aged 1 month to 1 year: 700 micrograms/kg once daily. Increase if necessary to 3mg/kg once daily (max of 20mg)
   - Omeprazole is available as Losec® MUPS® tablets (10mg and 20mg) and an oral suspension. Tablets are a licensed product (but not licensed for use in children except for severe ulcerating reflux oesophagitis in children over 1 year). Oral suspension (5mg/5ml, 10mg/5ml or 20mg/5ml) is an unlicensed liquid special. Dependent on dose required and age of infant, please consider use of Losec® MUPS® tablets in the first instance. Disperse tablets in water, and if needed mix with some fruit juice.
SECONDARY LACTOSE INTOLERANCE

SYMPTOMS AND DIAGNOSIS
- Usually occurs following an infectious gastrointestinal illness but may be present alongside newly or undiagnosed coeliac disease.
- Symptoms include abdominal bloating, increased (explosive) wind, loose green stools.
- Lactose intolerance should be suspected in infants who have had any of the above symptoms that persist for more than 2 weeks.
- Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis.

ONWARD REFERRAL
- If symptoms do not resolve when standard formula and/or milk products are reintroduced to the diet, refer to secondary or specialist care.
- Refer to the paediatric dietitian if the child is weaned and a milk free diet is required.

TREATMENT
- Treat with low lactose/lactose free formula for 4-8 weeks to allow symptoms to resolve. Rarely symptoms may last up to 3 months.
- Lactose free formula can be purchased over the counter in supermarkets at a similar price to standard formula and the GP should not prescribe.
- In infants who have been weaned, low lactose/lactose free formula should be used in conjunction with a milk free diet.
- Standard formula and/or milk products should then be slowly reintroduced to the diet.
- In children over 1 year who previously tolerated cow’s milk, suggest the use of lactose free full fat cow’s milk which can be purchased from supermarkets (e.g. Lactofree® brand).

REVIEW AND DISCONTINUATION OF TREATMENT
- Low lactose/lactose free formula should not be used for longer than 8 weeks without review and trial of discontinuation of treatment.

LOW LACTOSE/LACTOSE FREE FORMULA TO PURCHASE FROM SUPERMARKETS
- SMA® Lactose free From birth
- Aptamil® Lactose Free From birth – lactose free

NOTES
1. Primary lactose intolerance is less common than secondary lactose intolerance and does not usually present until later childhood or adulthood.
2. All lactose reduced or lactose free formula are unsuitable for CMA as they are whole protein formula or only partially hydrolysed.
3. Soya formula (SMA Wysoy®) should not routinely be used for patients with secondary lactose intolerance. It should not be used at all for those under 6 months due to high phyto-oestrogen content. It should only be advised in patients over 6 months who do not tolerate the formula suggested here. Parents should be advised to purchase this, if used, as it is a similar cost to cow’s milk formula and is readily available.
Comparative costs of infant formulae for prescription – Oct 2018 MIMS prices

<table>
<thead>
<tr>
<th>Cow’s milk allergy – for prescription</th>
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<tbody>
<tr>
<td><strong>Product</strong></td>
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<tr>
<td></td>
</tr>
<tr>
<td>Extensively hydrolysed formulae</td>
</tr>
<tr>
<td>Similac Alimentum®</td>
</tr>
<tr>
<td>Aptamil Pepti® 1</td>
</tr>
<tr>
<td>Aptamil Pepti® 2</td>
</tr>
<tr>
<td>SMA Althera®</td>
</tr>
<tr>
<td>Nutramigen® 1 with LGG®</td>
</tr>
<tr>
<td>Nutramigen® 2 with LGG®</td>
</tr>
<tr>
<td>Nutramigen® 3 with LGG®</td>
</tr>
<tr>
<td>Pepti-Junior®</td>
</tr>
<tr>
<td>Pregestimil Lipil®</td>
</tr>
<tr>
<td>Amino acid formulae</td>
</tr>
<tr>
<td>Nutramigen Puramino®</td>
</tr>
<tr>
<td>Neocate® LCP®</td>
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<tr>
<td>Neocate® Syneo®</td>
</tr>
<tr>
<td>Neocate® Junior</td>
</tr>
<tr>
<td>Pre-term infant formulae – for prescription</td>
</tr>
<tr>
<td><strong>Product</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>SMA® Gold Prem 2</td>
</tr>
<tr>
<td>Nutriprem® 2</td>
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<tr>
<td>SMA® Gold Prem 2 liquid</td>
</tr>
<tr>
<td>Nutriprem® 2 liquid</td>
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<tr>
<td>High energy formulae – for prescription</td>
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<tr>
<td><strong>Product</strong></td>
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<tr>
<td></td>
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<tr>
<td>SMA® High Energy</td>
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<tr>
<td>Similac® High Energy</td>
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<tr>
<td>Similac® High Energy</td>
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<tr>
<td>Infatrini®</td>
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<tr>
<td>Infatrini®</td>
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<tr>
<td>Infatrini Peptisorb®</td>
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<tr>
<td>Grey list formula – do not prescribe</td>
</tr>
</tbody>
</table>

Examples of retail costs of products to purchase from supermarkets or pharmacies – July 2018

<table>
<thead>
<tr>
<th>Thickened formulae, thickening formulae and thickener</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product</strong></td>
</tr>
<tr>
<td>SMA® Anti-Reflux</td>
</tr>
<tr>
<td>Cow &amp; Gate® Anti-Reflux</td>
</tr>
<tr>
<td>Aptamil® Anti-Reflux</td>
</tr>
<tr>
<td>HiPP Anti-Reflux</td>
</tr>
<tr>
<td>Enfamil AR®</td>
</tr>
<tr>
<td>Instant Carobel®</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lactose free formulae</th>
<th><strong>Presentation</strong></th>
<th><strong>Price</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Aptamil® Lactose Free</td>
<td>400g</td>
<td>£5.99</td>
</tr>
<tr>
<td>SMA® LF Lactose free</td>
<td>430g</td>
<td>£6.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Soya formula</th>
<th><strong>Presentation</strong></th>
<th><strong>Price</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>SMA® WySoy</td>
<td>860g</td>
<td>£12.95</td>
</tr>
</tbody>
</table>
**Dos and Don’ts of Prescribing Specialist Infant Formulae**

**Do:**
- Promote and encourage breast feeding where it is clinically safe and the mother is in agreement.
- Check any formula prescribed is appropriate for the age of the infant.
- Check the amount of formula prescribed is appropriate for the age of the infant (see page 2) and/or refer to the most recent correspondence from the paediatric dietitian.
- Review any prescription where the child is over 1 year old, the formula has been prescribed for more than 1 year, or greater amounts of formula are being prescribed than would be expected.
- Review the prescription if the patient is prescribed a formula for CMA but able to eat any of the following foods – cow’s milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee.
- Prescribe only 1 or 2 tins/bottles initially until compliance/tolerance is established.
- Remind parents to follow the advice given by the formula manufacturer regarding mixing of the formula and safe storage of the feed once mixed or opened.
- Refer where appropriate to secondary or specialist care - see advice for each condition.
- Refer where appropriate to the paediatric dietitians (Tel: 0300 300 1503).
- Seek prescribing advice if needed in primary care from the Medicines Optimisation Team (Tel: 01375 365811).
- Seek prescribing advice if needed in secondary care from the Basildon Hospital Medicines Information Centre, Pharmacy Department (Tel: 01268 593788).

**Don’t:**
- **Do not** add infant formulae to the repeat prescribing template in primary care, unless a review process is established to ensure the correct product and quantity is prescribed for the age of the infant.
- **Do not** suggest lactose free or low lactose formulae for infants with CMA.
- **Do not** suggest soya formula (SMA WySoy®) for those with CMA or secondary lactose intolerance. It is not suitable at all in those under 6 months due to high phyto-oestrogen content.
- **Do not** suggest goat’s milk and formulae made from it, sheep’s milk or other mammalian milks for those with CMPA or secondary lactose intolerance or other conditions covered in this guideline.
- **Do not** suggest rice milk for those under 5 years old due to high arsenic content.
- **Do not** suggest thickened formulae (e.g. SMA® Anti-Reflux, Aptamil® Anti-Reflux or Cow & Gate® Anti-Reflux formulae) or thickening formula (Enfamil AR®) with separate thickener (Instant Carobel®) or Gaviscon Infant® as this could lead to over thickening of the stomach contents.
- **Do not** prescribe medication such as ranitidine or omeprazole in conjunction with thickening formula (Enfamil AR®) if parents choose to purchase this, since the formulae need stomach acids to thicken and reduce reflux.
- **Do not** prescribe Instant Carobel® where this is being added to regular formula as a choice rather than using a pre-thickened formula. Parents should be encouraged to purchase it.
- **Do not** suggest Gaviscon Infant® if intestinal obstruction is suspected, or in pre-term neonates, or more than 6 times in 24 hours or where the infant has diarrhoea, vomiting, renal impairment or a fever, due to its sodium content. (See page 10)
- **Do not** suggest low lactose/lactose free formulae in children with secondary lactose intolerance over 1 year who previously tolerated cow’s milk, since they can use supermarket full fat lactose free milk e.g. Lactofree® brand.
- **Do not** prescribe formulae marked in this document as grey list formulae.
REFERENCES AND FURTHER READING

Cow's milk allergy:
NICE Clinical Guideline 116 Food Allergy in Children and Young People. 2011


Venter C. et al Clinical and Translational Allergy 2017; 7:26 Better recognition, diagnosis and management of non-IgE medicated cow’s milk allergy in infancy :iMAP an international interpretation of of the MAP (Milk Allergy in Primary Care) Guideline

iMAP guideline presentation algorithm: https://www.allergyuk.org/health-professionals/mapguideline#anchor1

iMAP management algorithm: https://www.allergyuk.org/health-professionals/mapguideline#anchor1

iMAP taking an allergy focused history document: https://www.allergyuk.org/assets/000/001/293/iMAP-Allergy-focused_History_original.pdf?1502804761

Royal College of Paediatrics and Child Health (RCPCH) Care pathway for food allergy http://www.rcpch.ac.uk/allergy/foodallergy


Vandenplas et al SAGE Open Medicine 2: 20503121452423 2014. A pilot study on the application of a symptom-based score for the diagnosis of cow’s milk protein allergy


World Allergy Organisation DRACMA guidelines 2010 (Diagnosis and Rationale Against Cow’s Milk Allergy)


Host A. Frequency of cow’s milk allergy in childhood. 2002; Ann Allergy Immunol;89 (suppl): 33-37.


Taylor R. et al Pediatric Allergy Immunol 2012;23:240-249

Canani R. et al Journal of Allergy and Clinical Immunology 2012;129:580-582


**Soya formula:**


**Rice milk:**
Food Standard Agency statement on arsenic levels in rice milk, 2009.

**Pre-term infants:**


**Faltering growth:**
https://www.nice.org.uk/guidance/ng75

**Gastro-oesophageal reflux Disease:**
NICE Guideline NG1 Jan 2015 Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people https://www.nice.org.uk/guidance/ng1


Gaviscon Infant® Summary of Product Characteristics:
http://www.medicines.org.uk/emc/medicine/21981

Losec® MUPS® Tablets 10mg Summary of Product Characteristics:
http://www.medicines.org.uk/emc/medicine/7249
Secondary Lactose Intolerance:

General:


BNF for Children 2017-2018 MIMS October 2018

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The health visitors of Essex Child and Family Wellbeing Service.
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